PRINCIPAL INVESTIGATOR'S SUPPLEMENTAL PROTOCOL CHECKLIST

FOR USE WHEN INVOLVING HUMAN PARTICIPANTS IN RESEARCH

Section	Notes	√
STATEMENT	Purpose Procedures Duration of participant involvement Experimental products or procedures (e.g., IND, IDE)	
RISKS	Physical	
	Social	
	Psychological	
	Economic	
	Other	
METHODS TO MINIMIZE RISKS	DSMB	
	Risk management plan	
ANTICIPATED BENEFITS		
RISK/BENEFIT RATIO		
VULNERABLE POPULATIONS	Pregnant women, human fetuses or neonates	
	Prisoners	
	Children	
	Mentally challenged	
	Economically deprived	
	Educationally deprived	
	Non-English speaking participants	
	Other	
INFORMED CONSENT IMPLEMENTATION PROCESS/ DOCUMENTATION OF INFORMED CONSENT		
JUSTIFICATION FOR WAIVER/ALTERATION OF INFORMED CONSENT		
JUSTIFICATION FOR WAIVER/ALTERATION OF *DOCUMENTATION* OF INFORMED CONSENT		
ASSENT IMPLEMENTATION PROCESS/ DOCUMENTATION OF		

Section	Notes	√
ASSENT (CHILDREN)		
PARENTAL PERMISSION IMPLEMENTATION PROCESS/DOCUMENTATION OF PARENTS'/GUARDIANS' PERMISSION		
JUSTIFICATION FOR WAIVER/ALTERATION OF PARENTAL/GUARDIAN PERMISSION		
PLAN FOR MONITORING THE INFORMED CONSENT/ASSENT/ PERMISSION PROCESS		
PROTECTION OF PRIVACY AND CONFIDENTIALITY	Privacy of individual	
	Confidentiality of data	
ASSURANCE/ CERTIFICATE OF CONFIDENTIALITY	Assurance of Confidentiality (308(d) PHS Act; protects both individuals and institutions)	
	Certificate of Confidentiality (301(d) PHS Act; protects only individuals	
EMERGENCY CARE/TREATMENT		
EXTRA COSTS TO PARTICIPANTS		
REIMBURSEMENTS/ INCENTIVES		
APPENDIX MATERIAL (RELEVANT SUPPLEMENTARY MATERIALS)	Recruitment letters Promotional announcements Notification letters Other	

PRINCIPAL INVESTIGATOR'S SUPPLEMENTAL PROTOCOL CHECKLIST GUIDE

FOR USE WHEN INVOLVING HUMAN PARTICIPANTS IN RESEARCH

RESEARCH STATEMENT

Statement of purpose, procedures, duration, experimental products or procedures: Provide a brief statement of the purpose of the study, the procedures to be used, the duration of participants' involvement (i.e., hours, days, years) and whether any experimental products or procedures will be used and what they consist of (see next item if IND or IDE).

FDA Investigational New Device (IND) or Investigational Device Exemption (IDE) information: If the study involves the use of an investigational new drug (IND) or investigational new device (IDE), provide the IND or IDE number and relevant information.

Description of risks (physical, social, psychological, economic, other) to the individual or group. Include methods to minimize risks: Define the nature, magnitude, probability, and duration of potential harm(s) that a person may receive by participating in this research. Describe steps that have been taken to minimize risks (e.g., data and safety monitoring board [DSMB]), including the use of sound research design and by using procedures already being performed on the participant or other routine procedures that will be provided to the participant. Include a risk management plan in your protocol, if applicable.

***Description of anticipated benefits to the research participant*:** Discuss benefits to research participants resulting from the research. Describe the steps that have been, or will be, taken to maximize benefits.

Description of the potential risks to anticipated benefit ratio: Justify that the potential risk are reasonable in relation to anticipated benefits and the importance of the knowledge that may reasonably be expected to result from the research.

Justification for involving vulnerable participant populations: If the study involves special populations, such as pregnant women, human fetuses or neonates, prisoners, or children, provide a justification for their use and include a section that specifically addresses the requirements of HHS regulations 45 CFR 46:

1. ***If human fetuses are included, see November 2001 revisions to Subpart B of 45 CFR 46.***
2. ***If pregnant women are subjects, see November 2001 revisions to Subpart B of 45 CFR 46.***
3. ***If human neonates are used, see November 2001 revisions to Subpart B of 45 CFR 46.***
4. ***If prisoners are participants, see Subpart C of 45 CFR 46.***
5. ***If children are participants, see Subpart D of 45 CFR 46.***

If study participants include a special or vulnerable population, such as the mentally incompetent, provide a justification for their use in terms of the purpose of the research. If planning to use non-English speaking participants in the study, include a statement on how

translation of documents into the target language(s) will be handled and how the consent process will work.

Procedures for implementing and documenting informed consent: Describe procedures for informing participants and methods to obtain and document consent.

Justification for waiver or alteration of informed consent: If informed consent will not be obtained or will be altered, describe the justification for a waiver. The justification must address the four criteria for waiving or altering consent:
1) the research involves no more than minimal risk to the participants,
2) the waiver or alternation will not adversely affect the rights and welfare of the participants,
3) the research could not practicably be carried out without the waiver or alteration, and
4) whenever appropriate, the participants will be provided with additional pertinent information after participation.

Justification for waiver of documentation of informed consent: If written informed consent will not be obtained, provide justification for obtaining consent through other means. The justification must address one of the two criteria for waiving documentation:
1) that the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality or
2) that the research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context. If the first criterion is used, describe the procedures to ensure participants' wishes regarding documentation linking them to the research will be ascertained and honored.

Description of procedures for implementing and documenting the assent process of children: Describe procedures for informing children and methods to document assent.

Description of procedures for implementing and documenting parents' or guardians' permission: Describe procedures for informing participants and methods to document parental permission.

Justification for waiver or alteration of parental/guardian permission: If parental/guardian permission will not be obtained or will be altered, describe the justification for a waiver.

Plan for monitoring the informed consent/assent/permission process: 45 CFR 46.111(6) states that "When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects." Explain procedures for involving an independent monitor (e.g., IRB member) to witness the consent process.

***Provisions for protecting privacy/confidentiality*:** Explain provisions for protecting study participants from being identified either directly or indirectly. If for any reason data identifying subjects will be published or released to persons outside of the project, explain why this is

necessary.

Statement about need or lack of need for Assurance or Certificate of Confidentiality: This refers to formal Assurances and Certificates of Confidentiality.

Emergency care: Explain the actions that would be taken in the event that an emergency develops during a study participant's involvement in the research.

Statement of extra costs to participants due to involvement in the study: Self explanatory.

Description and justification of reimbursements or incentives that will be used: Self explanatory.

Notifying participants of their individual results: Describe the process used to notify study participants of their results, including those of immediate importance. Include precipitating circumstances and whether or not counselors will be used. Also, append an individual notification of results section to the protocol.

Notifying participants of study findings: Explain whether the participant will be offered the option of receiving overall study findings and the form they will take.

APPENDIX MATERIALS

Include all relevant supplementary materials. All materials for use by participants must be written in lay language. All appendix material should be submitted in the order in which they will be used in the study. This aids the IRB in understanding the logic involved behind the use of appendix materials.

Announcements/advertisements, notification letters, videos, scripts, other information for participants: Recruitment literature should include the purpose of the research and the selection criteria for inclusion in the study, a straightforward and simple description of the study, potential risks and benefits, method of reimbursement for time and inconvenience, the location of the research, sponsoring agencies, the person to contact for further information, an estimate of the time per session and total time of participation.

Data collection forms
Questionnaires, interview schedules, observation plans, focus group discussion guides, etc.
Coding guidelines and definitions of themes/variables
Medical records and / or other abstraction forms
Request and authorization for release of medical records
Manuals for training study personnel.
Consent and assent forms